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#15

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/031,629	02/27/98	FAUSTMAN	11275/75537

HM32/1013

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EXAMINER
NOLAN, P

ART UNIT
1644

PAPER NUMBER

DATE MAILED: 10/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/031,629

Applicant(s)

Paustman et al.

Examiner

Noban

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Response

A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for response specified above is less than thirty (30) days, a response within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for response is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to respond within the set or extended period for response will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/28/99
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-64 is/are pending in the application.
- Of the above claim(s) 8-64 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-7 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3
- ☒ Notice of References Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Part III DETAILED ACTION

1. Claims 1-64 are pending.
2. Applicant's election of Group I, claims 1-7 in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
3. Claims 8-64 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 and 4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting diabetes by detecting a reduction in the proteolytic processing of NFκB, does not reasonably provide enablement for detecting any autoimmune disease by detecting a reduction in the proteolytic processing of NFκB. The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to use the invention commensurate in scope with these claims.

The specification discloses only one working example demonstrating the ability of detecting a reduction in the proteolytic processing of NFκB and correlating said reduction with an autoimmune disease. The state of the art, The Merck Manual of Diagnosis and Therapy, does not recognize the use of detecting a reduction in the proteolytic processing of NFκB for detecting all of the myriad amount of autoimmune diseases. In fact it is not art recognized that any one method of detection can be used to detect all autoimmune diseases. Since the breadth of Applicant's claims reads upon at least 60 recognized autoimmune disorders and there is no specific guidance or working examples to enable one of skill in the art to reasonably predict that detecting a reduction in the proteolytic processing of NFκB would correlate to a wide range of autoimmune disorders and the state of art as taught by The Merck Manual does not recognize the use of said detection method, it would be unpredictable and require an undue amount of experimentation to practice the full scope of Applicant's claimed

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invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-3 and 5-7 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,538,854. (A).

The '854 patent teaches the detection of Hashimoto's disease by detecting a defect in the proteosome in a biological sample and comparing said defect to a wild type proteosome to detect an autoimmune disease. When the claims are read in light of the specification, the term reduction of proteosome activity is interpreted broadly to encompass detecting genetic defects which then leads to irregular processing of proteosome products, such as the HLA-I protein.

The prior art teachings anticipate the claimed invention.

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

9. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Patrick J. Nolan
Patrick J. Nolan, Ph.D.
Primary Examiner, Group 1640
October 10, 2000